UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE PAULSBORO DERAILMENT CASES	:	**MASTER DOCKET NO.: 13-CV-784 (RBK/KMW)**
MICHELLE TRULUCK, *et al.*,	:	
Plaintiff,	:	**CASE NO. 1:13-CV-5763 (RBK/KMW)**
vs.	:	
CONSOLIDATED RAIL CORPORATION, *et al.*,	:	
Defendants.	:	

DEFENDANTS CONSOLIDATED RAIL CORPORATION, NORFOLK SOUTHERN RAILWAY COMPANY AND CSX TRANSPORTATION, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF OMOWUNMI OSINUBI, M.D.

Filed on behalf of Defendants,
Consolidated Rail Corporation,
Norfolk Southern Railway Company
and CSX Transportation, Inc.

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COME NOW Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc. ("Defendants"), by and through their counsel, Burns White LLC, and submit this Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Omowunmi Osinubi, M.D.

I. PRELIMINARY STATEMENT

Plaintiff, Abdeslam Sahla ("Plaintiff") has retained Omowunmi Osinubi, M.D., to provide expert testimony in support of his toxic-tort claims. Dr. Osinubi's opinions are intended to establish that Plaintiff's brief, acute exposure to vinyl chloride and its degradation products, particularly formaldehyde, from a November 30, 2012 train derailment in Paulsboro, New Jersey

caused him to develop nasal inflammatory disease and polyposis, as well as the need for medical monitoring for naso-sinus and liver cancer.

As explained below, Dr. Osinubi's expert analysis is littered with methodological shortcomings. With regard to general causation (whether vinyl chloride or formaldehyde can cause the alleged injuries), Dr. Osinubi does not follow a recognized scientific methodology, nor does she provide reference to the peer-reviewed scientific literature where her novel causation method has been discussed and validated. Furthermore, she has not systematically reviewed the available scientific evidence on any of the purported relationships she attempts to establish, and thus fails to provide any information on the many relevant studies she excluded. Dr. Osinubi provides no assessment of the quality of the few selected studies she cites, and provides no discussion of the challenges to the validity or applicability of those studies.

Her methodology for determining the dose of vinyl chloride or formaldehyde to which Plaintiff was exposed is equally flawed. Dr. Osinubi uses Paulsboro resident's subjective descriptions of symptoms and odor, coupled with inadequate data and demonstrably faulty assumptions that do not reflect the actual conditions at the time of the derailment. Her blind reliance on modeling data that she does not understand and cannot validate renders her opinions inadmissible.

Dr. Osinubi's approach to specific causation (whether vinyl chloride or formaldehyde actually caused Plaintiff's alleged injuries) fares no better. Having inappropriately ruled the derailment-related exposures "in" as a potential cause, Dr. Osinubi relies on raw temporality, subjective history, and speculative personal belief to reach her ultimate specific causation conclusion—that Plaintiff experienced his alleged nasal injuries as the result of his brief and limited exposure to vinyl chloride and its degradation products. However, Dr. Osinubi's specific

causation opinion fails to properly exclude the well-known, well-established causes of nasal polyps and inflammatory disease in his medical history.

Dr. Osinubi's medical monitoring opinions are similarly speculative and unreliable. They should be excluded because they are based on flawed and unsupported assumptions regarding the long-term risks of acute vinyl chloride and formaldehyde exposure and because she fails to establish that the proposed monitoring program is medically appropriate.

In the end, Dr. Osinubi's opinions are no more than subjective views without an objective scientific foundation. Her opinions are the product of litigation, not reliable application of generally accepted scientific methods and principles. Accordingly, the expert report, opinions and testimony of Dr. Osinubi should be excluded, as they fail to satisfy the *Daubert* standards and Fed. R. Evid. 702.

Additionally, all of the opinions contained in Dr. Osinubi's report, which are based in part on the National Transportation Safety Board "(NTSB") report, are improper and must be excluded. The probative value of such opinions is greatly outweighed by the probability that they will lead to unfair prejudice and jury confusion, thereby warranting exclusion under Fed. R. Evid. 403.

II. SUMMARY OF DR. OSINUBI'S QUALIFICATIONS AND OPINIONS

Dr. Osinubi is a medical doctor who is board certified in occupational and environmental medicine. *See* April 24, 2015 deposition of Dr. Osinubi at p. 14, attached hereto as Exhibit A. She is currently an Assistant Professor at the Rutgers University School of Public Health. *Id.* at 14-15. She is also the President of a company called "Occupational and Environmental Health Associates." According to the company's website, Dr. Osinubi provides medico-legal consulting services in occupational and environmental medicine. These services include clinical evaluations, peer review, and importantly, causation analyses. Prior to this case, however, Dr.

Osinubi has never been involved in any litigation relating to vinyl chloride, or treated any patients who had been exposed to vinyl chloride. *Id.* at 19.

Based on her deposition testimony and her expert report, dated April 8, 2015, attached hereto as Exhibit B, it appears Dr. Osinubi's proposed testimony in this matter will include the following opinions:

- Plaintiff had "substantial" exposures to "very high levels" of vinyl chloride as the result of the November 30, 2012 train derailment.
- Plaintiff's home and local travels within the first hour after the derailment were located in the region where he was more likely than not exposed to greater than 4,800 ppm of vinyl chloride and 100 to 10,000 mg/m3 of vinyl chloride degradation products.
- As the result of said exposures, Plaintiff developed chronic nasal mucosal inflammation, including turbinate hypertrophy and nasal polyps, which superimposed on his pre-existing nasal structure deformity from a remote history of nasal fracture, triggered, exacerbated and/or aggravated his nasal airway diseases to such a severe degree that he had near total occlusion of his nasal passages, thereby requiring surgery.
- Acute exposure to formaldehyde can cause nasal and sinus cancers. Medical monitoring is warranted based on Plaintiff's pre-existing history of benign nasal disease.
- Acute exposure to vinyl chloride can cause liver cancer. Medical monitoring is deemed medically necessary.

See generally, Osinubi Rep. and Osinubi Dep.

III. ARGUMENT AND CITATION OF AUTHORITIES

A. Standards For Evaluation Of A Motion To Exclude Expert Testimony.

It is well-established that district courts are to conduct a "rigorous" analysis to ensure expert evidence satisfies the *Daubert* requirements and Rule 702 of the Federal Rules of Evidence before admitting expert testimony or opinions into evidence. *See, e.g., Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993). Briefly stated, those requirements are: (1) the witness must qualify as an expert; (2) the testimony or opinions must be reliable; and (3) the

expert testimony or opinions must assist the trier of fact and "fit" the facts of the case. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).

With respect to the qualifications prong of the inquiry under Daubert and Rule 702, expert testimony should be excluded unless it is shown that the witness possesses sufficient specialized expertise in the field in which he or she is proffered as an expert. *Elcock v. Kmart Corp.*, 233 F.3d 734, 744 (3d Cir. 2000).

The reliability prong mandates "that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert*, 509 U.S. at 590). A court "is not required to simply 'take the expert's word for it.'" *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 563 (W.D. Pa. 2003). As this Court has explained, the Third Circuit has developed an eight-part test for evaluating the reliability or scientific validity of purported expert testimony: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *United States v. Schiff*, 538 F. Supp. 2d 818, 833 (D.N.J. 2008) (quoting *United States v. Mitchell*, 365 F.3d 215, 235 (3d Cir. 2004)).

Finally, the expert testimony has to "fit"—that is, the court must determine that the opinion "is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual

dispute." *Daubert*, 509 U.S. at 591. Expert testimony that does not relate to the specific issues before the trier of fact "is not relevant and, ergo, non-helpful." *Id.*

B. All Of The Opinions Contained In Dr. Osinubi's Report, Which Are Based In Part On The NTSB Report, Are Improper And Must Be Excluded.

Dr. Osinubi has improperly relied upon the NTSB Accident Report and Factual Report as the underlying basis for all of her opinions in this case. *See* Osinubi Rep. 2; *see also* Osinubi Dep. at 91 ("The NTSB said it, the levels were very high."). 49 U.S.C. § 1154(b) states that "[n]o part of a report of the Board, related to an accident or an investigation of an accident, may be admitted into evidence or used in a civil action for damages resulting from a matter mentioned in the report." 49 U.S.C. § 1154(b); see also 49 C.F.R. § 835.2 ("no part of a Board accident report may be admitted as evidence or used in any suit or action for damages growing out of any matter mentioned in such reports"). The clear language of 49 U.S.C. § 1154(b) mandates that expert reports based on NTSB reports, which rely on the information and conclusions contained in those reports, may not be introduced into evidence in a subsequent civil trial. *Louisiana ex rel. Dept. of Transp. & Dev. v. Kition Shipping Co., Ltd.*, 653 F.Supp.2d 633, 647–48 (M.D. La. 2009).

Recently in *Credle v. Smith and Smith, Inc.*, 42 F. Supp. 3d 596 (D.N.J. 2013), this Court faced the same issue arising here—permissibility of use by an expert of portions of an NTSB report. In *Credle*, the NTSB issued a Marine Accident Brief relating to the sinking of a scallop boat that sank off the coast of Cape May, New Jersey. The Brief included descriptions of the investigation, history of the vessel, conditions on the day of the sinking, probable cause of the incident, and a safety recommendation based on the results of the report. Plaintiff's expert based a number of his findings of fact and conclusions on information contained in the Marine Accident Brief. The defendants filed a motion *in limine* seeking to preclude the introduction of

any evidence that the NTSB issued in its Marine Accident Brief or any of the opinions and conclusion set forth in the Brief. The New Jersey District Court held that, while expert witnesses may in certain circumstances base their opinion on inadmissible evidence under the Federal Rules of Evidence, the clear language of Section 1154(b) mandates that expert reports based on NTSB reports, which rely on the information and conclusions contained in those NTSB reports, may not be introduced into evidence in a subsequent civil trial. Accordingly, the court granted Defendant's motion in limine.

Likewise, here, Dr. Osinubi improperly bases her opinions on inadmissible evidence from the NTSB reports. Plaintiff's attempt to sneak this inadmissible evidence into this trial through the report of her expert should not be permitted. As the Ninth Circuit has cautioned regarding inappropriate reliance on expert testimony, "if what an expert has to say is instead tangential to the real issues, the jury may follow the 'expert' down the garden path and thus focus unduly on the expert's issues to the detriment of issues that are in fact controlling." *Rogers v. Raymark Industries, Inc*., 922 F.2d 1426, 1431 (9th Cir. 1991). Here, any probative value of Dr. Osinubi's testimony would be substantially outweighed by the danger of unfair prejudice, confusing the issues, and misleading the jury. All of the opinions contained in her report, which are based in part on the NTSB report, are improper and must be excluded.

C. Dr. Osinubi's Opinions Must Be Excluded Because They Do Not Result From Reliable Principles Or Methodologies.

1. Dr. Osinubi Has Not Utilized A Scientifically Established Method to Determine Plaintiff's Alleged Exposure to Vinyl Chloride.

Daubert requires that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152 (1999). Dr. Osinubi clearly fails this test.

The scientific method of assessing cause-and-effect relationships between agents and health effects contrasts starkly with the lax reasoning employed by Dr. Osinubi in this case. In her report, Dr. Osinubi provides no references to the extensive literature on general causation methods. Indeed, the Bradford Hill criteria have been widely recognized by courts throughout the United States for their usefulness in providing a framework for identifying the generally accepted methodology for making determinations of medical causation. *See Federal Judicial Center's Reference Manual on Scientific Evidence, Third*. (2011) at 601-06 (providing descriptions of the Bradford Hill factors); *see also* Declaration of Michael I. Greenberg, MD, MPH, attached hereto as Exhibit C; Declaration of Douglas L. Weed, M.D., M.P.H., Ph.D., attached hereto as Exhibit D, Exhibit A at 23-26. The Bradford Hill factors include whether: (1) a temporal relationship exists; (2) the association is strong or weak; (3) a dose-response relationship exists; (4) the results have been replicated; (5) the association is biologically plausible; (6) alternative explanations have been adequately considered; (7) the association exhibits specificity; and (8) the findings are consistent with other knowledge. *See Magistrini v. One Hour Martinizing Dry Cleaning*, 180 *F.* Supp.2d 584, 592 (D.N.J.2002)(citing the Bradford Hill factors). The Bradford Hill criteria are key to determining whether an expert's causation opinion is reliable and based on sound scientific principles, or as here, is fatally flawed.

Here, Dr. Osinubi's theory, or hypothesis, that vinyl chloride exposure may be causally associated with any of the alleged injuries fails to satisfy the Bradford Hill criteria. *Id.* Although Dr. Osinubi recognizes the importance of Bradford-Hill criteria, even teaching it to her students, she curiously discredits and fails to apply this method in the course of this litigation. Osinubi Dep. at 282, 285. Instead, without citation to any scientific references supporting her position, Dr. Osinubi maintains that the criteria are inapposite to acute exposure situations such as the

Paulsboro derailment exposures. *Id.* at 285. *But see In re Breast Implant Litig*., 11 F. Supp. 2d 1217, 1234 n.5 (D. Colo. 1998) (while all factors of the Bradford Hill criteria need not be present to demonstrate causality, failure to address, much less follow, the Bradford Hill criteria renders an expert's methodology unreliable).

Her alternative "method," if any, fares no better. Dr. Osinubi has created her own novel general causation methodology for acute exposures that analyzes: 1) was the person exposed; 2) are the symptoms consistent with what we know about the health effect of the chemical; 3) how severe was the exposure and the symptoms; and, 4) is there a need for medical monitoring. *Id.* at 283-285. However, Dr. Osinubi provides no citation to any peer-reviewed scientific literature where this method has been discussed and validated.[1]

In fact, the simple presence of disease or symptoms following a potential for exposure does not in any way prove that any toxicant caused the disease in question. *See* Greenberg Declaration. This flawed logic, is known as *post hoc, ergo propter hoc* (or "following this therefore because of this"). *Id.* The medical illness is used as proof that there was sufficient exposure and dose, and this proof of exposure then becomes the basis for explaining the cause of the symptoms and the existence of the disease in question. *Id.* Such circular reasoning is not medically or scientifically sound and is not generally accepted by the scientific community. *Id.*; *see also Abbott v. Fed. Forge*, 912 F.2d 867, 875 (6th Cir. 1990) ("*[P]ost hoc, ergo propter hoc* is not a rule of legal causation.").

[1] In her deposition, Dr. Osinubi refers to an article entitled "Association or causation: evaluating links between "environment and disease"" by Robyn M. Lucas & Anthony J. McMichael. Osinubi Dep. at 287-290. Although that article suggests that Bradford Hill's criteria are not absolute, the article still acknowledges that they provide a framework against which exposures can be tested as component causes. The article does not espouse Dr. Osinubi's methodology.

It follows that Dr. Osinubi's opinions on general causation regarding the alleged acute and chronic health effects of vinyl chloride exposure or its degradation products lack an objective scientific foundation. As such, she offers nothing more than subjective opinions lacking in reliability. Further, because "there are no standards controlling the technique's operation," it is impossible to replicate or test her methodology, and the rate of potential error is infinite. *See Paoli,* 35 F.3d at 742.

2. Dr. Osinubi Has Not Properly Analyzed Plaintiff's Level Of Exposure, Which Renders All Of Her Causation Opinions Unreliable, Irrelevant And Inadmissible.

Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden in a toxic tort case. *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105 (8th Cir. 1996). "[A] plaintiff must prove level of exposure using techniques subject to objective, independent validation in the scientific community. At a minimum, the expert testimony should include a description of the method used to arrive at the level of exposure and scientific data supporting the determination." *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir.1998) (internal citations omitted).

Here, Dr. Osinubi's so-called methodology concerning the Plaintiff's alleged exposure levels amounts to mere guesswork. Dr. Osinubi is not able to quantify any alleged dose of vinyl chloride or decay products that Plaintiff may have been exposed to following the derailment. Osinubi Dep. at 113-114. Instead, Dr. Osinubi works backwards, opining that if someone had smelled vinyl chloride and experienced certain symptoms, then that person must have had excessive exposures. *Id*. at 114. ("The people who were closest to the exposure, to the extent that they were close to it, and they inhaled it, and got it on their skin, and they smelled it, and they

coughed, and they were-their skin burned, and they had the rash, and they developed asthmatic symptoms, absolutely they were exposed, and the exposure caused their symptoms.")

This backwards reasoning is a fatal flaw in her methodology. By reversing the process (Plaintiff has symptoms, therefore, the dose is sufficient), Dr. Osinubi has turned the science of toxicology on its head. Without first determining the Plaintiff's dose, she has improperly "ruled in" vinyl chloride as a cause of the alleged injuries.

Further, to the extent that Dr. Osinubi is opining that smelling an odor on the day of the Paulsboro train derailment is equivalent to an exposure of at least 3,000 ppm, such an opinion is speculative and lacks scientific reliability. *See* Weed Declaration, Exhibit A at 27-33. Odor threshold is not a valid and reliable technique for determining whether or not an individual has been exposed to vinyl chloride, the intensity of that presumed exposure, or any putative health effect of that exposure. *Id.* Furthermore, even if it is assumed that an individual was exposed to vinyl chloride and smelled an odor, this same technique is an unreliable estimate of the amount of vinyl chloride to which that individual may have been exposed. *Id.* Dr. Osinubi appears to have conceded this point at her deposition when she testified that "you cannot use odor thresholds to judge the level of exposure." Osinubi Dep. at 88.

3. Dr. Osinubi's Opinions Are Premised Upon Inadequate Data and Faulty Assumptions Contrary To The Circumstances Surrounding the Derailment.

As part of its role as gatekeeper, the district court must ensure that the underlying facts and/or data upon which a proffered expert's opinion are based are reliable in and of themselves. If an expert's opinion is based on unreliable facts, the opinion must be excluded. *See In re TMI Litig.*, 193 F.3d 613, 697 (3d Cir. 1999).

Under Fed. R. Evid. 703, "an expert can discuss as the basis for an opinion facts or data which are otherwise inadmissible hearsay, 'if of a type reasonably relied upon by experts in the

particular field in forming opinions or inferences upon the subject."' *Soden v. Freightliner Corp.*, 714 F.2d 498, 502 (5th Cir. 1983) (quoting Fed. R. Evid. 703). Concerns about the reasonableness of such reliance are especially heightened in certain situations. For example, one factor leading to greater scrutiny of an expert's reliance on hearsay materials is reliance on materials prepared by another person in an area beyond the expert's expertise. Such a scenario raises significant concerns about the ability to validate the materials upon which the expert relies. If the testifying expert is unqualified in the subject matter to which these materials pertain, the expert will be unable to properly validate them. *In re Imperial Credit Indus., Inc. Sec. Litig.*, 252 F. Supp. 2d 1005, 1012 n.5 (C.D. Cal. 2003). This, in turn, will prevent the materials relied upon from being "subjected to meaningful adversarial testing through cross-examination of [the testifying expert]." *Id.*; *see also TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732 (10th Cir. 1993).

Here, the ALOHA[2] model and the model prepared by Plaintiff's expert, Panos Georgeopolous, which are relied upon by Dr. Osinubi to purportedly establish the level of vinyl chloride exposure to Plaintiff, are admittedly beyond her area of expertise. Because she cannot adequately assess their scientific reliability or accuracy, she is forced to rely, blindly and uncritically, upon these sources.

For example, Dr. Osinubi states that Plaintiff's residence was located 0.8 miles from the derailment. Osinubi Rep. at 18. Her report references divergent models that give significantly different exposure estimates for this particular 0.8 mile distance. First, Dr. Osinubi's report references the National Oceanic and Atmospheric Administration (NOAA) plume modeling

[2] Areal Locations of Hazardous Atmospheres (ALOHA) is a free web-based software program for chemical release modeling. It is utilized by emergency responders to make reasonable evacuation decisions and was referenced in the National Transportation Safety Board ("NTSB") hearings.

conducted by the United States Coast Guard, which predicted that vinyl chloride concentrations would only have reached 250 ppm as far out as 0.8 miles. Osinubi Report at 11. However, Dr. Osinubi also references the ALOHA model, which predicted that the vinyl chloride concentrations could have exceeded 4,800 ppm as far out as 0.8 miles. *Id.* at 10. While Dr. Osinubi acknowledges in her deposition that there is a significant difference of thousands of parts per million between the two results, she goes on to state that she does not know which one is correct. Osinubi Dep. at 58, 61. Obviously, her decision to base her opinion on the model with the greatest level of exposure with no scientific basis to do so is troublesome. *See* Osinubi Rep. at 18.

In fact, the ALOHA model has several reliability limitations that Dr. Osinubi was admittedly not aware of. ("I don't know much about the ALOHA model. I rely on the information that was provided to me as correct information.") Osinubi Dep. at 34; *see also* Declaration of Lloyd L. Schulman, Ph.D., attached hereto as Exhibit E. ALOHA was developed as a tool to aid in real-time, emergency response to chemical spills. *See* Shulman Declaration. According to the ALOHA User's Manual, "[i]ts computations represent a compromise between accuracy and speed; ALOHA has been designed to produce good results quickly enough to be of use to responders." *Id.* "Wherever uncertainty is unavoidable, ALOHA will err in favor of overestimating rather than underestimating threat distances. *Id.* In some cases, *ALOHA will significantly overestimate threat zones*." *Id*. Even Plaintiffs' own modeling expert concedes that ALOHA models are not reliable predictors of concentration levels. *See* April 30, 2105 Deposition of Panos Georgopoulos at 178-181, attached hereto as Exhibit F.

Accordingly, the ALOHA model was not an actual reflection of the alleged exposures, but instead, a "worst case" modeling that did not incorporate the actual conditions, in particular

the wind direction, at the time of the derailment. In fact, even when accurate input information is available, ALOHA's results can be unreliable, and under some conditions, there are some effects that ALOHA does not model at all. *See* Schulman Declaration. According to the User's Manual, ALOHA's results can be unreliable when the following conditions exist: very low wind speeds, very stable atmospheric conditions, wind shifts and terrain steering effects, or concentration patchiness, particularly near the release source. *Id.* All of these conditions existed during the first hour after the vinyl chloride release. *Id.* There were additional problems with the ALOHA model: (1) this run did not correctly account for the amount and duration of the release; (2) the dispersion characteristics did not reflect the actual release because it used the computer clock time of 10:50 a.m. EST, instead of the actual derailment time of 7:00 a.m. EST; (3) no terrain is allowed in the run, so the model fails to account for the fact that vinyl chloride was trapped in the creek channel; and (4) the wind direction was modeled as north-northeast at two (2) knots, which was not the wind direction at the time of the accident. *Id.* Accordingly, the ALOHA results do not accurately portray the dispersion of vinyl chloride at the time of the derailment, and Dr. Osinubi should not be permitted blindly rely on the model to reach her conclusions.

Likewise, Dr. Osinubi's reliance on the modeling report of Plaintiff's expert witness, Panos Georgeopoulos, is also problematic. Like the ALOHA model, the results presented by Dr. Georgeopoulos are not an accurate representation of the transport and dispersion of vinyl chloride around Paulsboro. *Id.* To the extent Dr. Georgeopoulos is precluded from giving expert testimony due to his own methodological problems, Dr. Osinubi's opinion is likewise subject to exclusion.

Of particular concern in this matter is Dr. Osinubi's blind reliance on Dr. Georgeopoulos' model regarding the predicted time course dispersion of vinyl chloride and its decay products.

Osinubi Rep. at 12. She cites his report for the hypothesis that formaldehyde and hydrochloric acid are the main constituents of the decay products of vinyl chloride, and that both were present in concentrations high enough to have caused Plaintiff's alleged injuries and the risk of future cancer. *Id.* at 14-15. However, the Dr. Georgopoulos' modeling exercise does not include any actual formaldehyde measurements. Accordingly, there is no evidence provided by Dr. Osinubi that *any* formaldehyde was present after the Paulsboro train derailment at any location. Indeed, in her deposition, Dr. Osinubi concedes that she is not able determine actual exposure levels of hydrochloric acid or formaldehyde, if any, for any Paulsboro resident. Osinubi Dep. at 113-115. Nor was she aware of the Tuazon et al. (1988) article that does not report hydrochloric acid among the decomposition products of vinyl chloride. *Id.* at 111. Obviously, causation opinions based on substances that may not even have been present following the derailment have no basis in fact.

Undoubtedly, Dr. Osinubi's opinions are based on unreliable facts. Because she has no ability to assess the scientific validity of these models, Defendants are deprived of the ability to conduct an assessment through cross-examination of her. Moreover, since the models do not reflect the actual conditions at the time of the derailment, her opinions do not "fit" the facts of this case, thereby warranting exclusion.

4. Dr. Osinubi's Reliance On The New Jersey Department of Health Survey Renders Her Opinion Unreliable.

Also problematic is Dr. Osinubi's reliance on the New Jersey Department of Health ("NJ DOH") survey results. The NJ DOH prepared a report—called a "health consultation"—describing the results of surveys administered to residents of Paulsboro in the aftermath of the derailment. *See* Weed Declaration, Exhibit A at 11-15. Dr. Osinubi attempts to provide support

for her claims regarding possible acute health effects among Paulsboro residents by noting the following interpretation of the NJ DOH health survey:

> Health effects survey of Paulsboro residents conducted by the NJ DOH, showed that residents who were in high toxic threat zones and or smelled an odor from the incident were more likely to report symptoms such as headache, coughing, and irritation of nose and throat, dizziness, irritation or pain or burning eyes, and difficulty breathing. These symptoms are consistent with what is expected for acute over exposures to vinyl chloride.

Id. However, the self-administered NJ DOH survey is an extremely poor quality survey and cannot be relied upon. *Id.* It is subject to recall and other forms of information bias as well as confounding bias, both important threats to the internal validity of the survey. *Id.* Furthermore, no statistical testing or modeling was undertaken; as a result, any so-called "differences"—e.g. that one surveyed group had a higher percentage of symptoms than another—may have been due to chance. *Id.* Finally, even if all the foregoing serious methodological flaws are taken into account, the survey showed that in some instances, reported symptoms increased as the distance from the derailment site increased, a counterintuitive result. *Id.*

The methodological quality of individual studies of human populations can be assessed using a checklist developed by Downs and Black (1998). *Id.* at 13-14. This scale has high internal consistency and good inter-rater reliability, as well as good test-retest characteristics. The NJ DOH in-person and mailed survey scored a 3 out of a possible 27, an extremely low score. *Id.* Accordingly, the NJ DOH surveys of the Paulsboro population are of such poor quality that they cannot be relied upon. *Id.*

The fact that Dr. Osinubi fails to mention, much less discuss these many methodological flaws of the NJ DOH survey efforts is a good example of her subjective approach to what should be an objective scientific evaluation of the available evidence. *Id.*, Exhibit B at 9. There is too

great an analytical gap to jump from the DOH surveys to an opinion that Plaintiff's injuries were the result of her exposure to vinyl chloride.

5. Dr. Osinubi Cannot Establish General Causation—That Vinyl Chloride Or Formaldehyde Cause The Health Effects From Which Plaintiff Allegedly Suffers Or May Develop in the Future.

A central tenet of toxicology is that "the dose makes the poison." Bernard D. Goldstein and Mary Sue Henifin, *Reference Guide on Toxicology* in *Federal Judicial Center Reference Manual on Scientific Evidence* (hereafter, "*Reference Guide on Toxicology*"), at 636 (3d ed. 2011). This principle "implies that all chemical agents are intrinsically hazardous—whether they cause harm is only a question of dose." *Id*. Accordingly, an expert witness cannot establish that a plaintiff's exposure to a certain chemical was capable of causing his or her illness merely by citing studies in which far greater doses were shown to produce that illness. Instead, the expert must also be able to explain why extrapolation from higher doses to lower doses is scientifically valid under the circumstances presented. *Id*. at 646; *see also Baker v. Chevron*, 680 F. Supp. 2d 865 (S.D. Ohio 2010) (excluding expert's causation opinion based on multiple epidemiological studies in which the levels or durations of exposure were not comparable to those allegedly experienced by the plaintiffs).

Dr. Osinubi's report in this case cites a limited number of studies from various scientific periodicals and other government publications as support for her opinions that Plaintiff's exposure to vinyl chloride and decay products, particularly formaldehyde, are the cause of his nasal polyps and inflammation, as well as his increased risk of contracting naso-sinus or liver cancer in the future. None of these studies involve short-term acute exposure to vinyl chloride, and only one involves short term exposure to formaldehyde. As even Osinubi admits, there is "very little" or "little" data on chronic respiratory disease, liver disease, or cancer in populations exposed to what she calls "substantial or high levels of exposure to vinyl chloride for relatively

brief periods." Osinubi Rep. at 22, 24. Indeed, she cites no evidence—not a single epidemiological study, much less a body of epidemiological evidence—that examines the putative effect of short-term (i.e. less than an hour or two) exposure to vinyl chloride (at any exposure level) on naso-sinus chronic inflammatory disease, respiratory disease, liver disease, or cancer outcomes. *See* Weed Declaration, Exhibit B at 10.

> Q: So do you have any literature that indicates that short-term exposure, such as the one that occurred in Paulsboro, causes cancer?
>
> A: There is no literature that says that.

Osinubi Dep. at 159.

Her analysis with regard to formaldehyde and nasal mucosal irritation and polyps fares no better. These shortcomings are fatal to the admissibility of Dr. Osinubi's expert testimony and opinions here. Rule 702 jurisprudence recognizes that unsupported assumptions, unexplained or unjustified extrapolations, and leaps of faith or lapses in logic are badges of unreliable, speculative, and unscientific conclusions. Under these circumstances, the reliance on the referenced studies violates both the reliability requirements and the "fit" requirements of Rule 702.

i. Naso-Sinus Chronic Inflammatory Disease

According to her report, "[n]oxious environmental pollutants that are associated with chronic nasal inflammation including nasal polyposis and high levels of exposure to chemical/irritant inhalational hazards have been associated with chronic inflammation of the nasal passages and chronic sinusitis." Osinubi Rep. at 22. However, this is an unreferenced general association claim by Dr. Osinubi. Put another way, she provides no empirical support (i.e. no citations from the peer-reviewed literature) for her claim. *See* Weed Declaration, Exhibit B at 11.

Dr. Osinubi's opinion that acute exposure to formaldehyde can cause naso-sinus inflammatory disease and polyps does not receive much support in the literature. *See* Weed Declaration, Exhibit B at 11-12. Significantly, Dr. Osinubi references four articles in support of the proposition that formaldehyde exposure can cause polyps or inflammation. The Alexiou study, by Osinubi's own admission, does not specifically discuss formaldehyde, and makes no effort to separate formaldehyde exposure from other potential occupational exposures. Osinubi Dep. at 265; *see also* Weed Declaration, Exhibit B at 12. Further, it concludes that there is no sufficient evidence for the role of environmental and occupational exposure in the epidemiology of nasal polyps. *Id.* at 266-267. Ultimately, Dr. Osinubi's inclusion of this study provides no specific evidence of a relationship between formaldehyde exposure and nasal polyposis.

Likewise, the Collins article does not discuss formaldehyde. Rather, the study authors identified 1120 patients with polyposis who completed a questionnaire. *See* Weed Declaration, Exhibit B at 12. Significantly, exposure to formaldehyde was not recorded in the questionnaires. *Id.* As such, this study is irrelevant to the question of whether formaldehyde exposure is associated with nasal polyposis. *Id.*

Also unfounded is Dr. Osinubi's reliance on the Kim article, case-control study of nasal polyposis and exposure to woodstoves. This is not a study that examined whether exposure to formaldehyde was associated with polyposis, as no measurement of formaldehyde was undertaken. *Id.* Indeed, the authors only asked about "occupational exposures" to what they call "noxious inhalant compounds" not otherwise specified. *Id.* In the end, Dr. Osinubi's inclusion of this study provides no evidence of a specific relationship between formaldehyde exposure and nasal polyposis. Again, Dr. Osinubi is relying on dissimilar exposures to create her causation opinion.

In the end, Dr. Osinubi can only cite to one study which relates exposure to formaldehyde to nasal polyposis. *Id.* at 276. Instead, she basis her opinion on studies of what she terms "irritants in general." *Id.* It follows that Dr. Osinubi would have the reader believe that anyone exposed to occupational pollutants is at risk for nasal inflammation or polyps. However, it is not scientifically valid to rely on experiments involving dissimilar exposures to a different substance to reach causation conclusions concerning formaldehyde exposure. This type of unfounded assumption and unwarranted extrapolation, bordering on the *ipse dixit*, is textbook junk science. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Lasorsa v. Showboat*, 2009 WL 2929234 (D.N.J. Sept. 9, 2009). Accordingly, Dr. Osinubi's implied claims that exposure to formaldehyde causes naso-sinus chronic inflammatory disease or nasal polys should be excluded.

ii. Naso-Sinus Cancer

Dr. Osinubi also claims that formaldehyde "is known to cause several cancers, including naso-sinus cancer and leukemia." Osinubi Rep. at 15. For this assertion, she cites to a Fact Sheet from the website for the National Cancer Institute. *See id.* (citing National Cancer Institute. Formaldehyde Cancer Risk Fact Sheet, *available at*: http://www.cancer.gov/cancertopics/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet/print). That document, however, provides that a causal relationship between exposure to formaldehyde and naso-sinus/nasopharyngeal cancer has not been established—even as to those chronically exposed, such as funeral industry workers. *See* National Cancer Institute. Formaldehyde Fact Sheet (discussing chronic exposure and providing that some studies "have found an association [short of a causal relationship] between formaldehyde exposure and nasopharyngeal cancer, *although some other studies have not*" (emphasis added)).

Later in her report, Dr. Osinubi again claims that "[f]ormaldehyde exposure is causally associated with nasal and sinus cancers." Osinubi Rep. at 23 (citing Cancer research UK. Risks

and causes of nasal and sinus cancers, *available at:* http://www.cancerresearchuk.org/about-cancer/type/nasal-cancer/about/risks-and-causes-of-nasal-and-sinus-cancers). That webpage does state that research "suggests" that formaldehyde exposure may increase your risk for developing nasal and sinus cancers. *See* Cancer research UK. Risks and causes of nasal and sinus cancers. But here too, the webpage references occupational exposure, not acute exposure. *Id.* ("Research suggests that working in some jobs may increase your risk of developing cancers in the nasal cavity and paranasal sinuses."). Moreover, the webpage does not specifically discuss a single epidemiological study, much less the studies that found there is not even an association between chronic vinyl chloride exposure and naso-sinus cancer.

In short, Dr. Osinubi provides no evidence to support the existence of a causal relationship between acute exposure to vinyl chloride and naso-sinus cancer. Any testimony that such a causal relationship exists is utter speculation and would therefore be fundamentally unreliable.

iii. Respiratory Disease

Dr. Osinubi states that "[t]here is very little data available on the chronic respiratory effects of short-term or brief exposures to very high levels of vinyl chloride." Osinubi Rep. at 22.[3] So, she again relies on the example of chronically exposed vinyl chloride workers in an attempt to support her claim that acute exposure to vinyl chloride can cause chronic respiratory disease. *Id.* at 18. Dr. Osinubi does not, however, cite to a single study to support this assertion. Instead, she states that because the respiratory tract has a finite number of reactions to an infinite number of exposures to chemicals and irritants, "by analogy, it is expected" that acute exposure

[3] Of course, saying that "there is very little data available" implies that at least some data exists. Yet Dr. Osinubi cites nothing to support her implication.

to vinyl chloride can result in one or more long-term pulmonary condition. Osinubi Rep. at 18. Yet again, she cites no study or other evidence to support this opinion.

In sum, Dr. Osinubi provides no evidence, and so does not apply general causation methods, to any evidence demonstrating that any of the chronic respiratory health effects that she identifies have, in fact, been established as caused by exposure to vinyl chloride (regardless of the duration or intensity of exposure). *See* Weed Declaration, Exhibit B at 11.

iv. Chronic Liver Disease

Dr. Osinubi claims that acute exposure to vinyl chloride can cause toxicant-associated steatohepatitis ("TASH") and liver cirrhosis and, in addition, may also cause liver cirrhosis and liver cancer by working synergistically with co-occurring heath factors. Osinubi Rep. at 23-24. These opinions are fundamentally unreliable.

Dr. Osinubi's opinion that vinyl chloride exposure can cause toxicant-associated steatohepatitis ("TASH") is methodologically unsound and scientifically invalid. *See* Weed Declaration, Exhibit B at 14. The Saad study on which Dr. Osinubi relies involved vinyl chloride workers who were chronically exposed to vinyl chloride, not individuals who were acutely exposed, as was the case here. *Id.* Even if it were appropriate to rely on a single study of chronic exposure to draw such a causal connection to acute exposure (it is not), the study was poorly designed and highly flawed—it had no control for any known causal factors and risk factors of steatohepatitis, such as over-nutrition, excessive ethanol consumption, and exposure to other industrial chemicals. *Id*. Likewise, the Cave study on which Dr. Osinubi relies to support her assertion that vinyl-chloride exposure may increase susceptibility to infections and/or chronic inflammatory states, Osinubi Rep. at 21, involved workers that had been exposed to, on average, high levels of vinyl chloride for several years. Weed Declaration, Exhibit B at 14.

Dr. Osinubi's linking of vinyl chloride exposure to liver cirrhosis is also unsupported. *Id*. In fact, the evidence taken as a whole reveals there is no increased risk of liver cirrhosis, even in those chronically exposed to vinyl chloride. *Id.*; *see also* Elisa Frullanti, et al., *Vinyl Chloride Exposure and Cirrhosis: A Systemic Review and Meta-Analysis*, 44 DIGESTIVE AND LIVER DISEASE 775 (2012) (finding that "the epidemiologic evidence does not suggest an excess mortality from cirrhosis in vinyl chloride-exposed workers").

Last, Dr. Osinubi's claims regarding synergism are either unsupported by the evidence or are irrelevant to the plaintiffs in the Paulsboro matter. *See* Weed Declaration, Exhibit B at 36-38. Dr. Osinubi's claims that vinyl chloride exposure and diabetes or viral hepatitis work synergistically to cause liver cirrhosis is unsupported by any scientific literature. *Id*. Indeed, the studies that Dr. Osinubi cites to support her assertion simply do not discuss the extent to which vinyl chloride acts synergistically with diabetes or viral hepatitis in the occurrence of liver cirrhosis. The authors of the only study that addressed synergism found that there may be synergism between alcohol consumption and vinyl chloride exposure in causing liver cirrhosis, but only where the person consumes six alcoholic beverages per day and was exposed to at least 2,500 ppm of vinyl chloride for an entire year.

v. Vinyl Chloride Carcinogenesis

Dr. Osinubi's expansive claim that vinyl chloride exposure can cause cancer of the brain, lungs, and lymphohematopoetic systems, Osinubi Rep. at 24-25, is also not reliable. To support her claim, she cites to an outdated edition of the International Agency for Research on Cancer's summary of vinyl chloride. *Id.* at 20 (citing the 1997 edition). The most recent edition, published in 2012, does not recognize any connection between vinyl chloride exposure and cancer of the brain, lung, or lymphohematopoetic systems. *See* Weed Declaration, Exhibit B at 15. Indeed, after having had an opportunity to review the 2012 edition, Dr. Osinubi admitted at her May 8

deposition that the type of vinyl chloride exposure at issue here does not cause lung cancer. Osinubi Dep. 2 at 234-35.

Chronic exposure to vinyl chloride is linked with the risk of hepatic angiosarcoma, a rare type of liver cancer. *See* Declaration of Lee Hartner, M.D., attached hereto as Exhibit G; *see also* Weed Declaration, Exhibit A at 35. ("A causal relationship between vinyl chloride and angiosarcoma of the liver in human populations has only ever been observed in occupational groups involved in the manufacture and production of vinyl chloride."); NJ DOH Consultation Rep. at ix (discussing connection between chronic exposure to vinyl chloride and angiosarcoma of the liver, but no other cancer). In the context of acute exposure to vinyl chloride, however, there is no evidence-based study that definitively demonstrates the ability of brief vinyl chloride exposure to increase the risk of angiosarcoma of the liver. *See* Hartner Declaration.

Dr. Osinubi attempts to fill this critical data gap by relying on a study of rats and mice acutely exposed to vinyl chloride, some of whom developed non-malignant pulmonary growths. Osinubi Rep. at 24-25. The conditions of the study, however, do not in any way simulate the situation that occurred in Paulsboro on the day of the derailment. Greenberg Declaration. Moreover, although the study found that mice exhibited tumorogenic effects following exposure to extremely high doses of vinyl chloride, no such effects were found in rats that were similarly exposed. *Id.* These flaws notwithstanding, a single animal study simply cannot be used to estimate risks in human populations. *See* Weed Declaration, Exhibit B at 15. Dr. Osinubi's conclusion that acute vinyl chloride exposure may cause angiosarcoma is based on an analogy so dissimilar that it warrants exclusion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997) (rejecting expert testimony that plaintiff's cancer was due to exposure to PCBs when testimony was based on animal studies of infant mice that had developed cancer after exposure to PCBs).

D. Dr. Osinubi's Specific Causation Opinion Should Be Excluded Because Her Differential Diagnosis Fails To Adequately Account For Alternative Explanations.

The failure to make a valid scientific showing of general causation necessarily means that the record fails to establish specific causation, *i.e.*, that Plaintiff's alleged injuries were caused by exposure to vinyl chloride. *Soldo v. Sandoz Pharms. Corp*., 244 F. Supp. 2d 434, 565 (W.D. Pa. 2003) ("the issue of specific causation is material, however, only if plaintiff can demonstrate general causation..."). Further, it is well-established that an expert opinion fails the *Daubert* test of reliability when he or she fails to "adequately account[] for obvious alternative explanations." Fed. R. Evid. 702, Advisory Comm. Notes to 2000 Amend. (*citing Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994)). The Third Circuit has held that "where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable." *Paoli*, 35 F.3d at 759 n.27; *Heller*, 167 F.3d at 156.

Here, Dr. Osinubi admits that Plaintiff did not experience any health effects from the vinyl chloride exposure, nor does he have any current health complaints. *See* Osinubi Rep. at 2, 20. Instead, the only injury that Dr. Osinubi relates to the derailment is his chronic nasal mucosal inflammation, which triggered, exacerbated and/or aggravated his nasal airway diseases to such a severe degree that he had near total occlusion of his nasal passages, thereby requiring surgery. *Id.* at 23.

In fact, Plaintiff had a significant nasal fracture in his youth, which resulted in a significant twist to the septum. *See* Osinubi Dep. at 262. However, it is Dr. Osinubi's opinion that his prior injury had nothing to do with his need for subsequent surgery, instead relating it to his post-derailment exposures. *Id.* Likewise, she completely rules out that it might be a natural progression of scar tissue that developed out of his prior trauma. *Id.* at 277.

Here, Dr.Osinubi's was not fully informed on Plaintiff's prior medical history—a factor that is critical in a proper differential diagnosis. For example, one of the risk factors that for nasal polyps that predominates the literature is aspirin intolerance. However, Dr. Osinubi denies discussing with Plaintiff whether he has a history of aspirin use. *Id.* at 277. Likewise, she also fails to consider whether Plaintiff had a family history of nasal polyps, another know risk factor. *See* Weed Declaration, Exhibit B at 12. Dr. Osinubi also failed to consider the role that Plaintiff's exposure to Paulsboro refinery emissions may have played in his condition. *Id.* at 279.

Conveniently, Dr. Osinubi also neglects to mention that the authors of the NJ DOH survey, specifically mention that all of plaintiffs' symptoms, including irritation of the nose, have multiple causes and may have occurred as a result of anxiety, fear, or stress induced by a traumatic event. NJ DOH Survey, 2014, p. 12; *see also* Weed Declaration, Exhibit B at 9.

In the end, Dr. Osinubi acknowledges the other possible causes of Plaintiff's maladies, but her only basis for refuting other possible causes is her own say-so—an approach that fails to withstand even superficial scrutiny. *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 608 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003) ("'Judgment' does not substitute for scientific method; without a reliable method, result-oriented 'judgment' cannot be distinguished from scientifically or methodologically-based judgment").

Because of Dr. Osinubi's manifest failure to establish any reliable grounds for concluding Plaintiff's injury was caused by vinyl chloride or its degradation products and not something else, her opinions and testimony concerning them should be excluded. Her subjective and arbitrary rejections of established alternative causes in favor of the proffered litigation cause, based primarily on temporality, is precisely the type of subjective, unscientific opinion that fails to satisfy Rule 702.

E. Dr. Osinubi's Opinions Regarding Medical Monitoring Should Be Excluded As Speculative And Unreliable.

Dr. Osinubi recommends that Plaintiff obtain life-long medical monitoring for naso-sinus cancer with an ear nose and throat specialist and annual physician evaluations for health promotion and cancer prevention, with laboratory tests to be done on an as needed basis. Osinubi Rep. at 26. Dr. Osinubi's opinions should be excluded because they are based on flawed and unsupported assumptions regarding the long-term risks of acute vinyl chloride and formaldehyde exposure and because she fails to establish that the proposed monitoring program is medically appropriate.

1. Dr. Osinubi's Medical Monitoring Opinions Are Based On Flawed And Unsupported Assumptions Regarding the Long-Term Risks Of Acute Exposure To Vinyl Chloride And/Or Formaldehyde.

As discussed *supra* Section C.5, there is no causal relationship between acute exposure to vinyl chloride and/or formaldehyde and the future illnesses for which Dr. Osinubi claims Plaintiff must be monitored. For this reason alone, Dr. Osinubi's opinion as to Plaintiff's need for medical monitoring as a result of his exposure to vinyl chloride and/or formaldehyde is fundamentally unreliable. *See* Weed Declaration, Exhibit A at 35. ("A causal relationship between vinyl chloride and angiosarcoma of the liver in human populations has only ever been observed in occupational groups involved in the manufacture and production of vinyl chloride."). Put simply, Dr. Osinubi's opinion that Plaintiff is at risk for future disease based on his brief, acute exposure to vinyl chloride and/or formaldehyde is nothing more than "unsupported speculation." *In re Paoli R.R. Yard PCB Litig*., 35 F.3d at 742.

2. Dr. Osinubi Fails To Establish That The Proposed Monitoring Is Medically Appropriate.

Dr. Osinubi's medical monitoring opinions are also subject to exclusion for the independent reason that she provides no basis as to why the specific medical monitoring that she

recommends would be medically appropriate. *See* Weed Declaration, Exhibit A at 79. (To be recommended, the medical monitoring must be "effective," meaning that the test, coupled with the treatment, has been shown to reduce mortality in well-designed clinical trials); *Rowe v. E.I. DuPont De Nemours & Co.*, No. 06-1810, 2009 U.S. Dist. LEXIS 67389, at *32 (D.N.J. July 29, 2009) (holding that medical monitoring must be reasonable, necessary, and different than any other the plaintiff would otherwise undergo). Dr. Osinubi cites no evidence whatsoever in support of her opinion that "lifestyle" interventions will reduce Plaintiff's risk of developing liver cancer. Hartner Declaration. Absent any peer-reviewed studies showing that the monitoring recommended by Dr. Osinubi is beneficial, her opinion does not withstand the *Daubert* test. *See In re Ingram Barge Co.*, 187 F.R.D. 262, 266 (M.D. La. 1999) (rejecting expert testimony on medical monitoring under *Daubert* because the expert "could point to no studies or peer-reviewed literature which suggested that the testing and monitoring he recommends should be performed"). The lack of any risk-benefit analysis in Dr. Osinubi's report, such as to her recommendation that Plaintiff receive "life-long" monitoring from an ear, nose, and throat specialist, further underscores the patent deficiencies in her medical monitoring opinions. *See Hansen v. Mountain Fuel Supply Co*, 858 P.2d 970, 980 (Utah 1993) (holding that the expert must show that "administration of the test to a specific plaintiff is medically advisable for that plaintiff," and that the sought medical monitoring program fails if the "burdensome frequency of the monitoring procedure, its excessive price, or its risk of harm to the patient" outweighs the program's benefits).

In the end, all Plaintiff offers to support her medical monitoring claims is Dr. Osinubi's "say so." This is wholly insufficient. *See Soldo*, 244 F. Supp. 2d at 563 (holding that a court "is

not required simply to 'take the expert's word for it'"); *In re Ingram Barge Co.*, 187 F.R.D. at 266 (recognizing that data is required to support the proposed medical monitoring program).

F. The Probative Value Of Dr. Osinubi's Opinions Is Outweighed By The Danger Of Unfair Prejudice, Confusion Of The Issues, And Misleading The Jury.

In addition to meeting the reliability requirement of Rule 702 and *Daubert*, an expert's proffered testimony must also satisfy Rule 403. Even assuming that Dr. Osinubi's opinions are reliable under *Daubert* and Fed. R. Evid. 702, which they are not, her testimony should also be excluded under Fed. R. Evid. 403.

Rule 403 states that evidence, although relevant, may still be excluded from trial, if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury. In this case, the probative value of Dr. Osinubi's opinions is clearly outweighed by these concerns. "The role [of gatekeeper] is especially sensitive in cases 'where the plaintiff claims that exposure to a toxic substance caused his injury, [because a] jury may blindly accept an expert's opinion that conforms with their underlying fears of toxic substances without carefully understanding or examining the basis of that opinion.'" *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 24 (D. Mass. 1995).

In sum, Dr. Osinubi's testimony does not meet either the *Daubert* reliability standard or Rule 403's admissibility requirement. Therefore, this court should enter an order excluding her report and testimony at trial.

IV. CONCLUSION

For the foregoing reasons, Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc., respectfully request that this Honorable Court exclude the proffered expert testimony of Omowunmi Osinubi, M.D. Defendants also request that the Court convene a *Daubert* evidentiary hearing on this Motion.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of May, 2015, a copy of the within Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Omowunmi Osinubi, M.D. was served on all counsel of record via efile.

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